UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

| | | |
|---|---|---|
| EMD MILLIPORE CORPORATION, MILLIPORE AB, and MILLIPORE SAS, | ) | |
| Plaintiffs, | ) | CIVIL ACTION NO. 11-10221-DPW |
| v. | ) | |
| ALLPURE TECHNOLOGIES, INC., | ) | |
| Defendant. | ) | |

MEMORANDUM AND ORDER
September 17, 2013

Plaintiffs EMD Millipore Corporation, Millipore AB, and Millipore SAS (collectively, "Millipore") brought this action against defendant AllPure Technologies, Inc. ("AllPure"), alleging infringement of United States Patent No. 6,032,543 (the "'543 Patent"). The '543 Patent relates to a "device for introduction and/or withdrawal of a medium into/from a container, and more particularly to such devices for introduction and/or withdrawal of media into/from a container as are intended for use in areas with very strict requirements on low contamination risks inside the container and/or in the container environment." '543 Patent col. 1, ll. 5-11.

AllPure responded to Millipore's claim with a counterclaim seeking declaratory judgment of non-infringement of the '543 Patent and of the invalidity and/or unenforceability of the '543

Patent. Following the completion of fact discovery, I conducted a *Markman* hearing and construed relevant claim terms. *EMD Millipore Corp.* v. *AllPure Technologies, Inc. ("Millipore I")*, No. 11-10221, 2012 WL 4862772 (D. Mass. Oct. 11, 2012). AllPure now moves for summary judgment of noninfringement.

## I. BACKGROUND

### *A. The '543 Patent*

The '543 Patent includes 14 claims, of which Claim 1 is independent, and the remaining are dependent. '543 Patent col. 9, l. 15-col. 10, l. 61. Claim 1 covers:

> A device for one of introduction and withdrawal of a medium into a container having an aperture formed therein for receiving said device, said device comprising:
>
> > at least one removable, replaceable transfer member for transferring a medium into and out of the container, said transfer member comprising a holder, a seal for sealing said aperture, a hypodermic needle having a tip, said needle supported within said holder in a longitudinal direction thereof, wherein the seal has a first end comprised of a bellows-shaped part sealingly attached to said holder, and a second end comprising a self-sealing membrane portion interiorly formed at an end of said bellows part, said membrane portion for sealing said aperture of said container, wherein said bellows-shaped part surrounds said needle and is deformable in a longitudinal direction, said membrane portion pierceable by the tip of the needle to form a sealable channel;
> >
> > a fastening device for sealingly securing the transfer member via the seal with the aperture of the container, thereby forming a closed system, said fastening device comprising a flanged part sealingly secured in the aperture and formed with

> at least one hole therethrough in communication with an interior of said container, a magazine part for removable securement of said at least one transfer member, and a fastening and centering means for removable locking of the magazine part to a flanged part in a position wherein the membrane portion sealingly abuts against the hole of the flanged part so as to accept the hypodermic needle for introduction into and withdrawal from the container through the membrane portion and the hole.

*Id.* col. 9, ll. 15-46.

The specification explains that, during certain stages in the production of products within fields such as pharmaceuticals and biotechnology, there is a continuous need for sampling of media or for the addition of regulating or active media. *Id.* col. 1, ll. 12-19. "When such production is carried out under conditions of low contamination requirements with respect to the media that are taking part in the process, the production normally is carried out in a sealed container. However, contamination risks arise when a medium is to be added to or a sample be withdrawn from the container." *Id.* col. 1, ll. 19-24.

Prior to the '543 Patent, most means of minimizing contamination risks were ineffective, costly, or both. The '543 Patent aimed to solve these problems through a device that would protect the medium and the environment from contamination, ensuring that representative samples could be consistently taken and allowing the device to be used anywhere and not just in so-called "clean rooms." *Id.* col. 2, ll. 20-47.

### *B. The AllPure TAKEONE Device*

The allegedly infringing device is the AllPure TAKEONE sampling system. Like the device claimed in the '543 patent, the TAKEONE device attaches to a container to allow sterile transfer of media. AllPure provides depictions in Figures B and C, showing the device before and after depression of the tab (12), respectively:

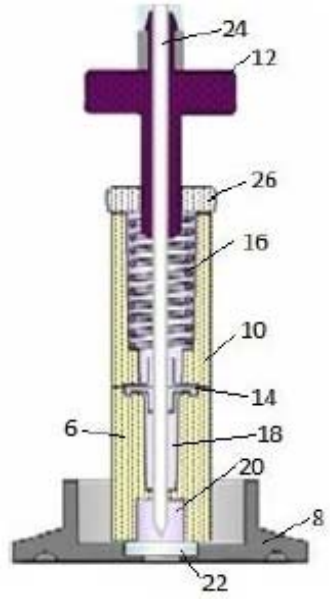



FIGURE B

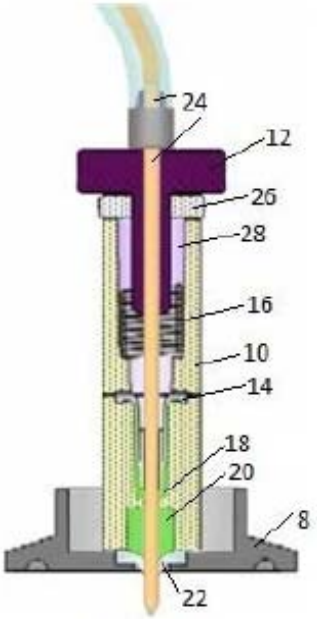



FIGURE C

The device operates by attaching its tank mount (8) to a container. When the tab (12) is pressed down toward the top cap (10), the spring (16) compresses, the diaphragm (14) stretches, and the needle attached to the cannula (24) moves down through

the holder (6). The cannula/needle (24) pierces the septum (22) and enters the container, allowing withdrawal of media.

A single TAKEONE device includes several of the transfer mechanisms just described. The device is delivered fully assembled and sterilized, and is meant to be disposed of following use.

## II. STANDARD OF REVIEW

Fed. R. Civ. P. 56 "mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp.* v. *Catrett*, 477 U.S. 317, 322 (1986). The question is whether, viewing the facts in the light most favorable to the nonmoving party, there is a "genuine dispute as to any material fact." Fed. R. Civ. P. 56(a); *Casas Office Machines, Inc.* v. *Mita Copystar Am., Inc.*, 42 F.3d 668, 684 (1st Cir. 1994).

"To prove infringement, the patentee must show that an accused product embodies all limitations of the claim either literally or by the [doctrine of equivalents]." *Amgen Inc.* v. *F. Hoffman-LA Roche Ltd.*, 580 F.3d 1340, 1374 (Fed. Cir. 2009). There can be no literal infringement if any claim limitation in the '543 Patent is absent from the accused TAKEONE device. *Bayer AG* v. *Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir.

2000). Even without literal infringement of a certain claim limitation, however, Millipore may establish infringement under the doctrine of equivalents if an element of the TAKEONE device "performs substantially the same function in substantially the same way to obtain the same result as the claim limitation." *AquaTex Indus., Inc.* v. *Techniche Solutions*, 419 F.3d 1374, 1382 (Fed. Cir. 2005) (internal quotation and citation omitted).

In short, AllPure is entitled to summary judgment of noninfringement if no reasonable fact-finder could find that the TAKEONE device embodies every claim limitation in the '543 patent, either literally or by the doctrine of equivalents. *Ethicon Endo-Surgery, Inc.* v. *U.S. Surgical Corp.*, 149 F.3d 1309, 1315 (Fed. Cir. 1998)

## III. ANALYSIS

AllPure argues that the TAKEONE device lacks at least three of the limitations in Claim 1 of the '543 patent, namely: (1) a seal having "a first end comprised of a bellows-shaped part sealingly attached to [a] holder," '543 Patent col. 9, ll. 23-25; (2) a seal having a "second end comprising a self-sealing membrane portion interiorly formed at an end of [a] bellows part," *id.* col. 9, ll. 25-27; and (3) a "removable, replaceable transfer member," *id.* col. 9, l. 18. AllPure also argues that Millipore is judicially estopped from asserting that the TAKEONE device infringes the '543 patent.

### *A. Judicial Estoppel*

I address at the threshold AllPure's argument that Millipore is judicially estopped from arguing that the TAKEONE device infringes the '543 Patent. "[J]udicial estoppel applies when a party has adopted one position, secured a favorable decision, and then taken a contradictory position in search of legal advantage." *Alternative Sys. Concepts, Inc.* v. *Synopsys, Inc.*, 374 F.3d 23, 33 (1st Cir. 2004) (internal quotation and citation omitted). The positions taken must be "directly inconsistent, that is, mutually exclusive." *Muskat* v. *United States*, 554 F.3d 183, 196 (1st Cir. 2009). The doctrine applies when a party obtains a favorable order from the PTO based on statements the party later seeks to repudiate in judicial proceedings. *Lampi Corp.* v. *Am. Power Products, Inc.*, 228 F.3d 1365, 1377 (Fed. Cir. 2000).

At issue here are representations Millipore made to the PTO in May 2006 while prosecuting another patent application for a "fluid sampling kit for aseptically retrieving a fluid sample from a fluid receptacle." In arguing that the '543 Patent did not render its invention obvious, Millipore stated:

> [The '543 Patent] fails to teach or suggest a fully assembled kit for sample taking that is sterile within its interior and which is simply placed into the port, the outer face of the assembly is then sterilized in place and after use the entire device is thrown away. Instead, [the '543 Patent] reuses the fastening device (3) which is then reloaded with disposable collection assemblies. There is no teaching or suggestion except in the present invention that

> one could make a truly disposable, presteri[li]zed sampling device and such a device absent the teachings of the present invention would not have been obvious to one of ordinary skill in the art from the teachings and suggestions of [the '543 Patent].

The PTO thereafter granted Millipore's application, which became U.S. Patent No. 7,293,477. AllPure argues that Millipore, having received favorable action based on its representations, cannot now argue the TAKEONE presterilized, disposable sampling device infringes the '543 Patent.

Millipore emphasizes that it only represented the '543 Patent did not "teach or suggest" a presterilized, disposable sampling device, meaning the '543 Patent could not serve as invalidating prior art for such a device. Nevertheless, Millipore argues, the '543 Patent may still ***cover*** a disposable, presterilized sampling device such that the device infringes the '543 Patent. In other words, Millipore conceded that a presterilized, disposable sampling device would be patentable notwithstanding the '543 Patent, but not that such a device necessarily would avoid infringement of the '543 Patent. The Federal Circuit has recognized - odd or rare as the circumstance may be - that a device may be patentable over prior art without avoiding infringement as a matter of law. ***See Festo Corp.*** v. ***Shoketsu Kinzoku Kogyo Kabushiki Co.***, 493 F.3d 1368, 1379 (Fed. Cir. 2007); ***Nat'l Presto Indus., Inc.*** v. ***W. Bend Co.***, 76 F.3d 1185, 1191-92 (Fed. Cir. 1996). Millipore thus has not taken

mutually exclusive positions and is not estopped from arguing that the TAKEONE device infringes the '543 Patent.

The dispositive question in this case, to which I now turn, is whether the TAKEONE device embodies all of the claim limitations in the '543 Patent.

### *B. The Seal*

The '543 patent claims "a seal" with two ends, the "first end comprised of a bellows-shaped part sealingly attached to said holder" and the "second end comprising a self-sealing membrane portion interiorly formed at an end of said bellows part." '543 Patent col. 9, ll. 20-27. Millipore identifies the "seal" in the TAKEONE device as the area between the diaphragm (14) and the septum (22), within what AllPure calls the holder (6). Millipore asserts that "[t]he self-sealing membrane portion is sealingly attached to the bellows-shaped part ***via*** the walls of a chamber in the magazine, isolating the samples from the environment and each other." AllPure contends the TAKEONE device lacks the required elements of either end of the seal.

#### 1. Self-Sealing Membrane Portion Interiorly Formed at an End of a Bellows-Shaped Part

I construed "a self-sealing membrane portion interiorly formed at an end of said bellows part," '543 Patent col. 9, ll. 25-27, to mean "a self-sealing membrane portion sealingly attached to the bellows-shaped part . . . at an end of said bellows part." ***Millipore I***, 2012 WL 4862772, at *9. Millipore

identifies the septum (22) as a self-sealing membrane portion, and the diaphragm (14) as a bellows-shaped part consistent with this court's construction of that term as "a part in which longitudinal deformation is enabled by at least one plate-like member." *Id.* at *6. Even so, the TAKEONE device does not literally infringe the limitation that the membrane portion be "interiorly formed . . . at an end of" the bellows part.

As reflected in my construction of "interiorly formed" to mean "sealingly attached," the "interiorly formed" limitation alone imposes no requirement that the membrane portion and bellows part be directly connected to each other. Rather, "attached" implies only that there be some means by which those parts are "ma[d]e fast or join[ed]," Webster's New International Dictionary 140 (3d ed. 1986); "fasten" in turn means "to cause to hold to something else," *id.* at 826. A reasonable jury could find that the septum (22) and diaphragm (14) are joined via the holder (6), which creates a sealed chamber with the respective parts at either end.

A requirement of direct connection is imposed, however, by the limitation that the membrane portion be formed or attached "at an end" of the bellows part. The septum (22) is at an end of the *seal*, taken as a whole, but is plainly not at an end of the diaphragm (14). Rather, at the ends of the diaphragm (14) are the top cap (10) and the cannula/needle (24). The parties'

disputes about precisely what it means for the membrane portion to be "interiorly formed" or "sealingly attached" are irrelevant for purposes of literal infringement, given that there is no question that the septum (22) is not formed or attached "at an end" of the diaphragm (14).

There remains, however, the question of infringement under the doctrine of equivalents. Despite language in my claim construction order that might be taken otherwise, prosecution history estoppel does not prevent Millipore from asserting the doctrine of equivalents as to this claim limitation.

Prosecution history estoppel applies when a patentee has filed an amendment seeking to narrow the scope of a claim, and "the reason for that amendment was a substantial one relating to patentability." *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1366 (Fed. Cir. 2003) (en banc). Although it is clear that Claim 1 was narrowed to allow the device to be patented over prior art, it was not narrowed so as to disclaim all multi-part seals.

In order to make its device patentable over prior art, Millipore amended Claim 1 to include the limitations of Claims 2-4. The prior iteration of Claim 1 had already required that the seal be mounted to the transfer member, but the internal components of the seal itself--such as the membrane portion and bellows part--were described only in Claim 3. Claim 3 also

included a requirement that the membrane portion be "connected to the bellows-shaped part." As incorporated into Claim 1, "connected to the bellows-shaped part" was rephrased to read "interiorly formed at an end of said bellows part." As discussed above, "at an end" imposes a limitation of direct connection not present in "connected to" or "interiorly formed" standing alone. The amendment thus narrowed the scope of Claim 1.

Any such limitation against multi-part seals, however, was not substantially related to patentability. Millipore represented to the PTO that, after the incorporation of Claims 2-4 into Claim 1, it "believes the present claims are now allowable and distinguishable over [prior art cited by the patent examiner in his earlier rejection of Claim 1] because none of the references show or disclose a seal formed like the present one, which is attached to the transfer member, thereby allowing independent operation of each holder between the inserted or withdrawn positions." For purposes of patentability, then, the importance of incorporating limitations on the elements of the seal from Claim 3 into Claim 1 was to ensure that the seal, as attached to the transfer member, would nevertheless allow for independent operation. In other words, the amendment prevents Millipore from claiming devices with a seal, attached to a transfer member, that does not allow for independent operation of each holder. Otherwise, however, the amendment has no relevance

for purposes of evaluating possible equivalents to the internal components of the seal described in the plain claim language--such as whether the membrane portion and bellows part may be separate pieces so long as the seal is preserved.

There is no indication that the TAKEONE seal prevents independent operation of the transfer mechanism between its "inserted" and "withdrawn" positions, such that Millipore would be estopped from arguing the device infringes the '543 Patent under the doctrine of equivalents. The TAKEONE device also maintains a sealed area between the diaphragm (14) and septum (22) while allowing for independent operation. Unlike the '543 Patent, the TAKEONE device achieves these functions without direct connection between the membrane portion and the bellows part. But a reasonable jury could conclude that the "differences between the two [devices] are insubstantial," *AquaTex*, 419 F.3d at 1382, and thus there remains a triable issue on infringement under the doctrine of equivalents as to this element of the claim.

2. Bellows-Shaped Part Sealingly Attached to a Holder

AllPure also argues that the TAKEONE device lacks "a bellows-shaped part sealingly attached to [a] holder," because the diaphragm (14) is not sealingly attached to the tab (12), which encloses the upper end of the cannula/needle (24). Millipore argues that the diaphragm (14), although not attached

to the tab (12), is sealingly attached to the top cap (10), which also encloses the upper end of the cannula/needle (24).[1]

AllPure argues that the TAKEONE tab (12) must be the "holder," and thus the lack of attachment between the tab (12) and the diaphragm (14) precludes literal infringement. Claim 1 of the '543 Patent specifies that the "needle [is] supported within [the] holder in a longitudinal direction." '543 Patent col. 9, l. 22. AllPure says that only the tab (12) secures the cannula/needle (24), and that the cannula/needle (24) merely passes through the retainer (26), top cap (10), and holder (6). But AllPure's own President affirmed that the "cannulas (24) . . . are secured to the tab assemblies (12) ***and to the top cap (10)*** and holder (6)." Zumbrum Decl. ¶ 11 (emphasis added). In any event, although the word "support" has "a variety of uses with the general meaning or suggestion of . . . holding up the weight or pressure of, and of forestalling sinking," Webster's New

[1] There is an alternative argument for literal infringement not made by Millipore. Although not attached to the diaphragm (14), the tab (12) is attached to the spring (16), which is also arguably a bellows-shaped part, as reflected in materials previously submitted by Millipore's expert Alexander Slocum. Millipore would then have to construe the entire structure contained by the top cap (10) and holder (6) as the "seal," to match the limitation that the seal have ends comprised of a bellows-shaped part and a membrane portion, respectively. This seems no less plausible than the construction of the "seal" already discussed above. In any event, this translation of the components of the TAKEONE device into the claim limitations of the '543 patent similarly flounders on the limitation, discussed below, that the device have a removable, replaceable transfer member.

International Dictionary 2297 (3d ed. 1986), "support" may also imply "stabilizing," *id.* In the latter sense, a reasonable factfinder could conclude that the top cap (10) supports the cannula/needle (24) in the longitudinal direction, even if the parts are not directly secured or attached.

Moreover, even absent literal infringement because only the tab (12) constitutes the "holder," a triable dispute would remain as to infringement under the doctrine of equivalents. Again, the TAKEONE device accomplishes contamination-free withdrawal of media by (as relevant for purposes of this claim limitation) maintaining a sealed area between the diaphragm (14) and septum (22), which is part of or at least attached to a transfer mechanism capable of independent operation. Unlike the '543 Patent, the TAKEONE device does so using two parts allowing for longitudinal deformation--a spring (16) and a diaphragm (14)--rather than one. Only the former is attached to the tab (12), while only the latter forms an end of the seal. A reasonable jury could conclude there is no substantial difference between the single bellows attached to the holder, as described in the '543 Patent, and--assuming the spring (16) can properly be called a bellows--the dual-bellows structure of the TAKEONE device. *Cf. Toro Co.* v. *White Consol. Indus., Inc.*, 266 F.3d 1367, 1370 (Fed. Cir. 2001) (factfinder may deem insubstantial

separation of what patentee claimed as one component into two components).[2]

For reasons similar to those discussed in Section III.B.1, above, the prosecution history does not estop Millipore from asserting infringement under the doctrine of equivalents. Although the bellows part is not directly attached to the holder, the seal as a whole remains attached to and a part of the transfer mechanism. Moreover, the separation of the bellows part and holder does not affect independent operation of the transfer mechanisms. The narrowing amendment of Claim 1 thus does not preclude the assertion of equivalence on this claim limitation. There remains a genuine dispute of fact as to whether this limitation of the '543 Patent has been infringed under the doctrine of equivalents.

### *C. Removable, Replaceable Transfer Member*

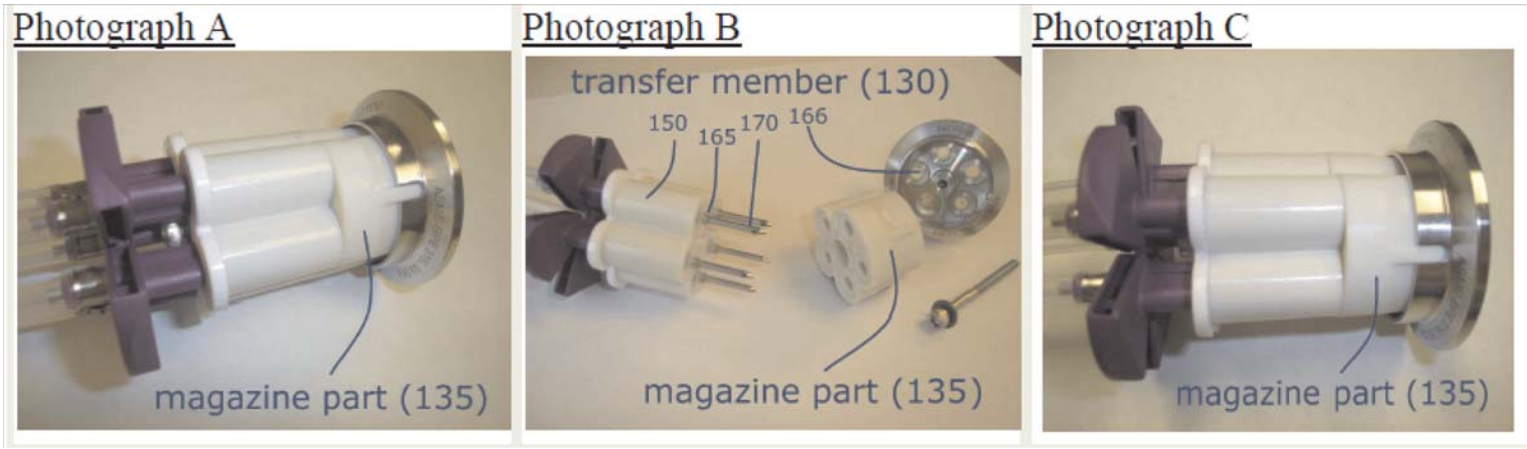
Although there are triable issues as to the infringement of claim limitations regarding the seal, at least under the doctrine of equivalents, I find the TAKEONE device lacks a "removable, replaceable transfer member" as claimed in the '543 Patent. For

[2] AllPure contends that this structure causes the TAKEONE device to function differently from the '543 Patent, in that it fails to prevent withdrawn samples from contacting the magazine. But this function is only important to the extent that transfer members are removable and replaceable, and thus that the magazine is reusable; this argument is essentially a re-casting of the argument that the TAKEONE device lacks a removable, replaceable transfer member, an argument that I address below.

this reason, AllPure is entitled to summary judgment of noninfringement.

The '543 Patent claims a "transfer member comprising a holder, a seal . . . [and] a hypodermic needle . . . supported within said holder." '543 Patent col. 9, ll. 20-21. At least one transfer member must be "removable and replaceable" from the "magazine part," which "removably secures at least one transfer member." '543 Patent col. 9, ll. 1, 38-39; ***Millipore I***, 2012 WL 4862772, at *5.

Millipore provides photographs to support its argument that the TAKEONE device embodies this claim limitation:




Photograph B purports to illustrate a transfer member as removed from the magazine part. Millipore re-characterizes AllPure's holder (6) as the magazine part, labeled as (135) in all three

photographs.[3] Millipore argues that the transfer member is "removably secured" by the holder (6) in the sense that the holder (6) secures the various component parts of a transfer member and, therefore, secures the transfer member as a whole.

In this context, however, "remove" most naturally means "to move . . . by taking away or off" or to "put aside, apart, or elsewhere." Webster's New International Dictionary 1921 (3d. ed 1986). "Take off" and "put apart" are significantly different from "take apart"; the former imply movement or separation of something as a whole, whereas the latter implies deconstruction.

[3] I will continue to use the labels and numbering suggested by AllPure in Figures B and C, above, as I have throughout this memorandum. For meaningful comparison, however, I provide a key to the elements of the TAKEONE device as labeled and numbered by each party:

| **Millipore** | **AllPure** |
|---|---|
| Holder (150) | Top Cap (10) |
| Bellows Part (165) | Diaphragm (14) |
| Needle (170) | Cannula/Needle (24) |
| Self-Sealing Membrane (166) | Septum (22) |
| Magazine Part (135) | Holder (6) |
| Transfer Member (130) | Essentially the entire device: Tab (12), Retainer (26), Top Cap (10), Diaphragm (14), Cannula/Needle (24), Holder (6), Septum (22), Tank Mount (8) |

The problem with Millipore's characterization of "removal" of a transfer member, then, is the absence of necessary component parts of the transfer member once it is removed from its securement by the magazine part. Again, the '543 Patent claims a transfer member "comprising" a holder, seal, and needle. The use of "comprising" indicates that the transfer member may have additional elements, but must at least have a holder, seal, and needle. *CIAS, Inc.* v. *Alliance Gaming Corp.*, 504 F.3d 1356, 1360 (Fed. Cir. 2007) ("In the patent claim context the term 'comprising' is well understood to mean 'including but not limited to.'"). Thus the claim limitation of a "removable, replaceable transfer member" means that the part of the device removable from the magazine part must have all of the component parts--a holder, needle, and seal.

Notably absent, however, from Millipore's depiction of a removed transfer member (Photograph B) is a "seal," as defined in the '543 Patent. Recall that Millipore characterizes the seal as the area between the diaphragm (14) and the septum (22), within the holder (6). Logically, however, the holder (6) cannot be both a part of the transfer member (*i.e.*, as a component of the seal) and also the part of the device from which the transfer member is removed (*i.e.*, the magazine part). This is borne out in Millipore's depiction in Photograph B of the holder (6) as separated from the various elements associated with the top cap

(10)--including diaphragm (14), and cannula/needle (24)--and from the tank mount (8) and septum (22). Upon separating the holder (6) from the various other elements, there ceases to be a seal, as defined in the '543 patent, with two ends comprising a bellows and a membrane, respectively. What Millipore characterizes as removal of a transfer member from the magazine part is, in fact, disassembly of a transfer member as defined in the '543 patent.

Neither is it possible for Millipore to maintain a claim for infringement under the doctrine of equivalents, because the purportedly removable transfer member(s) of the TAKEONE device do not serve the same function or function in the same way as those in the '543 patent.

The "first object" of the '543 Patent was "to provide a device for introduction and/or withdrawal of a medium into/from a container, according to which the medium upon and following withdrawal is protected from contamination from the environment." '543 Patent col. 2, ll. 20-24. The '543 Patent served this purpose even upon removal of a transfer member, because a transfer member constitutes a "closed, sealed system." ***Id.*** col. 6, l. 26. Similarly, the patent describes how, when using a prior-art device, "a small amount of the medium will always accompany the hypodermic needle as the latter is withdrawn from the membrane. In this manner the area exteriorly of the container is exposed to contamination risks." ***Id.*** col. 1, ll.

46-50. Another object of the '543 patent was thus "to provide a device for introduction and/or withdrawal of a medium into/from a container, according to which the environment is protected from contamination from the medium being withdrawn." '543 Patent col. 2, ll. 26-30. And, again, because a transfer member remained self-contained even upon removal from the magazine part, the environment was protected from contamination even upon removal of the transfer member--including the magazine part, which could be re-used.

However, if a TAKEONE transfer member is "removable" only in the manner described by Millipore, it cannot also function to protect the sample or the environment from contamination. When the top cap (10) and associated elements are separated from the holder (6) and the tank mount (8), the "seal" is broken, at which point the device fails to protect the sample from contamination through the tip of the needle, and also fails to protect the environment from contamination by any amount of medium withdrawn along with the needle. At the very least, a removable TAKEONE transfer member does not function in the same way as a '543 transfer member, insofar as some intermediate step of independently sealing the needle and/or sterilizing the interior of the transfer member would be necessary before it could be unsecured from the holder cum magazine part (6).

The TAKEONE device thus does not literally infringe, nor does it provide an infringing equivalent of the "removable, replaceable transfer member" claimed in the '543 patent. For this reason, summary judgment of noninfringement must enter for AllPure.

## IV. CONCLUSION

For the reasons set forth more fully above, defendant's motion for summary judgment of noninfringement is GRANTED, declaring that the AllPure TAKEONE device does not infringe United States Patent No. 6,032,543.

***/s/ Douglas P. Woodlock***
DOUGLAS P. WOODLOCK
UNITED STATES DISTRICT JUDGE